DE NOVO CLASSIFICATION REQUEST FOR
ThermoNeuroModulation (TNM) Device

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Thermal vestibular stimulator for headache.** A thermal vestibular stimulator for headache is a prescription device used to stimulate the vestibular system by applying thermal waveforms through earpieces placed in a patient's ear canal for the treatment of headache.

NEW REGULATION NUMBER: 21 CFR 882.5893

CLASSIFICATION: II

PRODUCT CODE: QAR

BACKGROUND

DEVICE NAME: ThermoNeuroModulation Device

SUBMISSION NUMBER: DEN170023

DATE OF DE NOVO: April 18, 2017

CONTACT: Scion NeuroStim, LLC
3105 Cone Manor Lane
Raleigh, NC 27613

INDICATIONS FOR USE

The TNM Device is intended to stimulate the vestibular system using tightly controlled thermal waveforms. The TNM Device is indicated for the prophylactic treatment of episodic migraine in adolescent and adult patients 12 years or older.

LIMITATIONS

For prescription use only.

The safety and effectiveness of this device has not been demonstrated in the following patient populations:

- history of cardiovascular disease;
- active and unstable mood or anxiety disorders;
  patients with active ear infections of a perforated tympanic membrane (eardrum).

The TNM device should not be used by pregnant women.

The long-term effects of using the TNM device are unknown.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The TNM Device is a non-invasive, home-use, DC-powered medical device that consists of an over-the-ear Headset with earpieces that protrude into the external ear canals, a Control Unit with resistive touchscreen display, and a power cord. Optional accessories include a wedge pillow to support reclining during each treatment in place of a firm pillow, a stylus pen that can be used in place of a fingertip to interact with the display and prism spectacles that may be worn to enable reading and other visual relaxation activities during treatment.

Figure 1: ThermoNeuroModulation Device Components

The TNM device uses a set of controlled thermal waveforms delivered to the anodized aluminum earpieces. The graph below indicates the thermal fluctuation delivered to the ear pieces on each side (left and right) of the headset. The fluctuations interact with the patient's vestibular system, causing changes which can be used to treat migraine headaches.

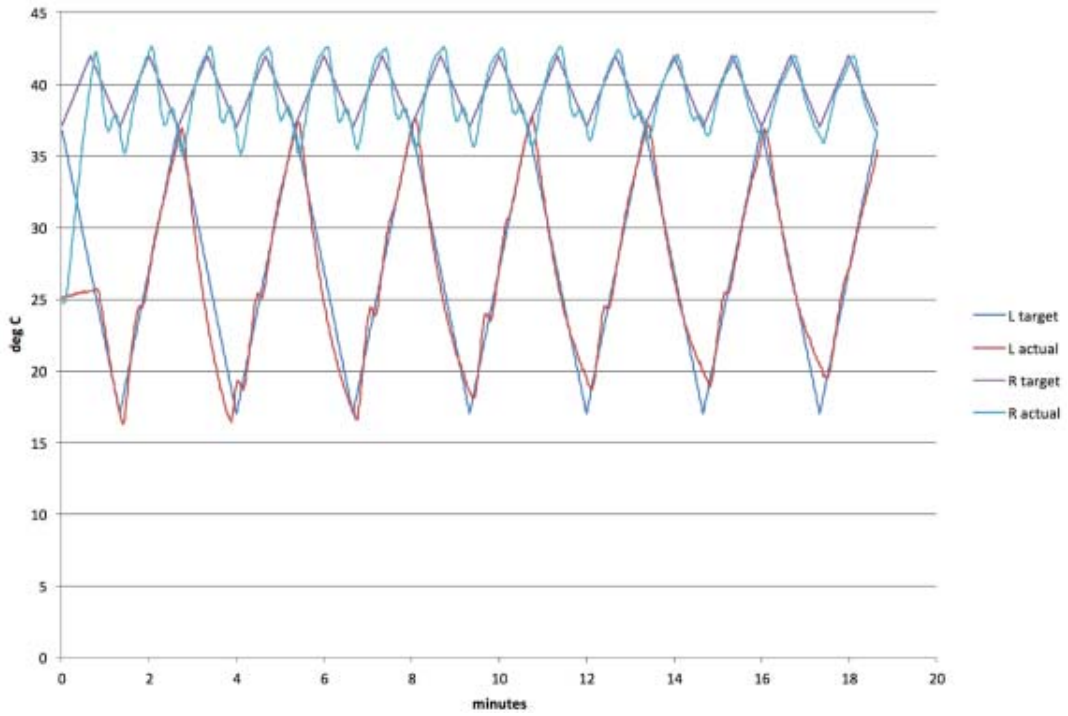

Figure 2: Thermal Waveforms of TNM Device

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The TNM device is considered a limited duration (≤ 24 hrs) intact skin contacting device. The FDA guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" recommends cytotoxicity, sensitization, and irritation or intracutaneous reactivity tests for intact skin contacting devices with limited duration (≤ 24 hr). The sponsor conducted all three recommended tests on the patient contacting components of the device including the earpad, earpiece base, and earpiece tip. The cytotoxicity (per ISO 10993-5), guinea pig maximization of sensitization (per ISO 10993-10) and dermal irritation (per ISO 10993-10) tests were conducted in accordance with GLP regulations (21 CFR § 58). All test results passed.

SHELF LIFE/STERILITY

The TNM device is not provided sterile, nor are any of the components to be sterilized by the end user. Cleaning of the device using 70% isopropyl alcohol was validated by a GMP-compliant study to demonstrate that the device can be sufficient cleaned using this method. Cleaning and maintenance instructions for the headset and earpieces of the TNM device are included in the labeling.

The sponsor provided information to demonstrate that the device components should meet or exceed the expected use life of 2000 hours.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The TNM device has not been tested for MRI compatibility and should not be used in an MRI suite.

The TNM device was tested in accordance with the following consensus standards and passed the following electromagnetic compatibility (EMC), electrical, mechanical, and thermal safety tests:

Table 1: EMC and electrical safety testing completed for the TNM device

Standard	Name
IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007)	Medical Electrical Equipment; Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2 Edition 3: 2007-03	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
IEC 60601-1-11:2010	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1:2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 62366:2007	Medical devices -- Application of usability engineering to medical devices

SOFTWARE

The TNM device is controlled by software. The software is consistent with a "MODERATE" level of concern, as discussed in the FDA guidance document entitled "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

PERFORMANCE TESTING – BENCH

The non-clinical testing for the TNM device consisted of verification and validation testing of hardware and software for the device and verification of the device thermal waveform output. Bench testing of the TNM device included the following:

- Temperature Profile and Rate
- Headset Cable Stress Test
- Earpiece Temperature Limit

- Heatsink Temperature Limit
- Accelerated aging for Earpads and Headband
- Critical Electrical Component Mean Time Between Failure Analysis
- Shipping and Transport Simulated Environment and Post-ISTA Functional Testing

SUMMARY OF CLINICAL INFORMATION

Summary

Scion NeuroStim, LLC conducted a multi-center, triple-blinded, placebo-controlled, randomized pivotal study for adjunctive prophylactic treatment of episodic migraine headache. The study included patients age 18-65 years of age with 4-14 attacks per month, diagnosed with episodic migraine headache at least six months prior to enrollment. The migraine diagnosis was consistent with the International Classification of Headache Disorders-II (ICHD-II) guidelines. Subjects must have had at least three consecutive months of stable migraine headaches, no changes in medication usage for three months leading up to the study, and no new medications introduced during the study. If subjects were already taking a prophylactic migraine medication they were allowed to continue medication as long as it met the criteria above (no changes in 3 months leading up the study, and no changes during study). There were no serious adverse events observed during the clinical study. Additionally, the sponsor proposed extrapolation of the data to support use of the device in patients age 12 years and older due to the high degree of similarity between adolescent and adult migraine symptoms and treatment options.

Inclusion Criteria

- The patient must have been diagnosed with episodic Migraine Headache at least six months prior to entering into the Study, consistent with the International Headache Classification of Headache Disorders-II (ICHD-II) guidelines.
- The patient must have a history of at least three consecutive months of stable Migraine Headaches prior to entering the Study. The patients will not have had changes in medication usage for the three Months leading up to the Study, nor will they introduce new medications during the Study period. Patients will satisfy these criteria: On a Monthly basis, at least four, and not more than a total of fourteen (4-14), Headache Days of which between four and fourteen (4-14) are Migraine Headache Days.
- The patient must not have failed on more than two classes of properly administered prophylactic pharmaceutical therapies for migraine headache. The patient may be on a single migraine prophylactic as long as the dosage has not been altered within three months of starting the Study and the dosage must not be altered for the duration of the Study;

Exclusion Criteria

Individuals who:

- are pregnant
- have a history of cardiovascular disease
- work night shifts
- have been diagnosed with vestibular migraine

- have been diagnosed with migraine with aura
- have menstrual migraine exclusively
- have been diagnosed with post-traumatic migraine
- have a history of unstable mood disorder or unstable anxiety disorder
- use a hearing aid
- have a cochlear implant
- have chronic tinnitus
- have temporomandibular joint disease
- have been diagnosed with traumatic brain injury
- have been diagnosed with neurological disease other than Headaches
- have a diagnosed vestibular dysfunction
- abuse alcohol or other drugs
- are experiencing medication overuse Headaches (individuals with respect to whom the Investigator is concerned that analgesic abuse is involved based on the ICHD-II guidelines).
- are less than 18 years old or greater than 65 years old
- have had eye surgery within the previous three months or ear surgery
- within the previous six months
- have active ear infections or a perforated tympanic membrane
- have participated in another clinical trial within the last 30 days or are
- currently enrolled in another clinical trial
- are using Botox treatments for migraines.
- Though not excluded, patients taking anti-histamines or anti-nausea drugs will be encouraged not to take such medications within four hours prior to a CVS-M treatment. The Investigator should review other medications taken by the patient with properties that mimic anti-nausea or antidizziness drugs as these may reduce responsiveness of the vestibular system to thermal vestibular stimulation. Such medications should also be avoided within four hours prior to a CVS-M treatment.

Concomitant Medications

- The use of acute abortive medications for the symptomatic treatment of migraine headache was allowed. Subjects could use their usual acute abortive medications, but medications were not allowed to be changed during the clinical trial.
- The patient could to take a single migraine prophylactic if the dosage had not been altered within three months of starting the Study and the dosage could not be altered for the duration of the Study. The patient must not have failed on more than two classes of properly administered prophylactic pharmaceutical therapies for migraine headache. Prophylactic medications used to treat other medical conditions were allowed, at the Investigator's discretion, if the subject was taking a stable dose for at least three months prior to screening and continued throughout the study.

Study Endpoints

Primary Efficacy Endpoint

- For active-treatment subjects as a group: During the third Month of the Treatment Period, their average total number of Monthly Migraine Headache Days will be lower than their comparable averages derived from the Pre- Treatment Baseline Period.

Secondary Efficacy Endpoints

- The number of active-treatment subjects having a reduction of 50% or more in Migraine Headache Days during the third Month of the Treatment Period as compared with the Pre-Treatment Baseline Period will exceed the number of placebo-treatment patients having that response rate.
- For active-treatment subjects as a group: During the third Month of the Treatment Period, their average Total Monthly Headache Pain Scores will be lower than their comparable averages derived from the Pre- Treatment Baseline Period.
- For active-treatment subjects as a group: During the third Month of the Treatment Period, their average number of Treated Headaches will be lower than their comparable averages derived from the Pre-Treatment Baseline Period.
- For active-treatment subjects as a group: On average, in comparison with their Pre-Treatment Baseline Period, they will have at the end of the Treatment Period, improvement in scores associated with the Quality of Life and Cognition Assessment measures.

Safety Endpoint

The principal safety endpoint for the Study is to verify the absence of material dizziness, with the associated risk of falls, as a consequence of using the active-treatment device. The Berg Balance test was used to assess any changes in balance performance as a result of device usage. Transient nausea and minor dizziness were experienced by some patients, as is sometimes reported in the diagnostic CVS literature.

Treatment Parameters

Active Treatment

- A standardized CVS time-varying waveform lasting approximately 19 minutes was used for all active treatment patients at all Pivotal Study sites. Treatments were administered twice daily. The two daily treatments were separated by at least one hour.
- The waveform schedule for active treatment patients consisted of a warm sawtooth delivered to one ear and a cold sawtooth delivered to the other ear. The warm sawtooth fluctuated from body temperature to 42 °C, and the cold sawtooth fluctuated from body temperature to 17 °C. The two waveforms were delivered simultaneously, but with different oscillation frequencies. After each two-day period, the warm and cold waveforms were switched so that the opposite ears will be treated with the different thermal vestibular stimulation. Thus every two days the ear receiving the cold stimulus was switched to the warm stimulus and vice versa.

Placebo Treatment

- A standardized CVS time-varying waveform lasting approximately 4 minutes was used for all placebo treatment patients at all Pivotal Study sites. Treatments were administered twice daily. The two daily treatments were separated by at least one hour.

- The waveform schedule for placebo treatment patients consisted of turning on the cooling fans and leaving the earpieces unpowered for a ~4-minute period.
- The earpiece tips were covered with EVA rubber to prevent cooling of the ear canal by the metallic earpieces.

Adverse Events

Table 2: Adverse Events by Group below shows the type and incidence of adverse events experienced by patients during the clinical study.

Table 2: Adverse Events by Group

Adverse Events (AEs)	**Active**	**Placebo**	**Partially active placebo**
Randomized subjects (n)	**50**	**30**	**20**
Serious adverse events	0	0	0
Unexpected adverse events	0	0	0
Nausea and/or dizziness	5	1	3
Ear discomfort, itch, irritation, pruritus	2	1	1
Tinnitus/buzzing	2	2	0
Neck pain exacerbation	1	0	0
Increased migraines/headaches	1	0	1
Blood pressure change during treatment	1	0	0
Eye twitching	0	1	0
Blurred vision	0	0	0

The demographics of the study participants are shown in Table 3 below.

Table 3: Demographics of Clinical Study Subjects

Demographics	Per protocol		Intention-to-treat (original)		Intention-to-treat (carry-forward percentage)		Randomized		
	Active	Placebo	Active	Placebo	Active	Placebo	Active	Placebo	Partially-active Placebo
n	30	18	39	19	45	21	50	28	40
Age (years)	45.4 ± 1.9	39.3 ± 3.2	44.4 ± 1.7	39.6 ± 3.1	44.1 ± 1.6	41.0 ± 2.9	44.4 ± 1.7	42.1 ± 2.4	40.7 ± 2.7
Baseline migraine days	7.7 ± 0.5	6.9 ± 0.7	7.7 ± 0.4	6.9 ± 0.7	7.9 ± 0.4	7.6 ± 1.1	7.6 ± 0.4	6.8 ± 0.6	8.7 ± 0.6
Baseline prescribed abortives taken	7.6 ± 0.8	6.1 ± 1.6	7.3 ± 0.7	6.1 ± 1.6	6.5 ± 0.7	5.0 ± 1.4	6.4 ± 0.7	4.3 ± 1.1	5.8 ± 1.0
Disease duration (years)	25.7 ± 2.4	20.6 ± 2.8	25.5 ± 2.0	21.2 ± 2.7	24.5 ± 1.8	21.6 ± 2.5	24.0 ± 1.7	22.0 ± 2.4	19.8 ± 2.0
Sex									
Male, n (%)	4 (13.3%)	2 (11.1%)	5 (12.8%)	2 (10.5%)	6 (13.3%)	2 (9.1%)	6 (12.0%)	2 (7.1%)	23 (15.0%)
Female, n (%)	26 (86.7%)	16 (88.9%)	34 (87.2%)	17 (89.5%)	39 (86.7%)	19 (90.9%)	44 (88.0%)	26 (92.9%)	17 (85.0%)
Education (years)	16.1 ± 0.5	15.5 ± 0.6	15.5 ± 0.6	15.5 ± 0.6	16.0 ± 0.4	15.8 ± 0.5	16.0 ± 0.4	15.4 ± 0.6	15.8 ± 0.5
Concomitant medications taken for any indication									
Antiepileptics (AEDs)	5 (17.9%)	2 (11.1%)	6 (15.4%)	2 (10.5%)	9 (20.0%)	3 (14.3%)	12 (24.0%)	5 (17.9%)	7 (35.0%)
β blockers/antihypertensives	4 (14.3%)	6 (33.3%)	5 (12.8%)	7 (36.8%)	8 (17.8%)	8 (38.1%)	10 (20.0%)	9 (32.1%)	5 (25.0%)
NA or DA drugs	8 (28.6%)	4 (22.2%)	9 (23.1%)	4 (21.1%)	5 (11.1%)	32 (9.5%)	7 (14.0%)	1 (3.6%)	1 (5.0%)
Anti-depressant/anti-anxiety	8 (28.6%)	6 (33.3%)	9 (23.1%)	7 (36.8%)	9 (20.0%)	6 (28.6%)	12 (24.0%)	8 (28.6%)	2 (10.0%)
None of the above	7 (23.3%)	7 (38.9%)	9 (23.1%)	8 (42.1%)	12 (26.7%)	9 (42.9%)	21 (42.0%)	13 (43.3%)	10 (50.0%)

Note: Randomized data excludes two chronic migraineurs randomized in error. Data are presented as n (%) or mean ± standard error of the mean or (at far right) as individual values for subjects (for chronic migraineurs randomized in error).

The results of the study showed improvement in migraine headache days and in migraine headache pain in the active treatment group. Specific data regarding the Primary and Secondary study Outcomes are shown in Table 4 and Table 5 below. Graphical representation of the change in monthly migraines displayed as change in monthly migraine and % change in monthly migraine are shown in Figure 3.

Table 4: Primary Outcomes Excluding Subjects >15 Monthly Headaches

	Per protocol		Intention-to-treat**	
	Active	**Placebo**	**Active**	**Placebo**
n	28	18	34	18
Migraine days (baseline compared to third month of treatment)				
Migraine days (baseline)	7.4 ± 0.5	6.7 ± 0.7	7.4 ± 0.4	6.7 ± 0.7
Migraine days (third month)	3.8 ± 0.5	5.8 ± 1.0	4.1 ± 0.5	5.8 ± 1.0
Change in migraine days (third month - baseline)	-3.6 ± 0.7	-0.9 ± 0.7	-3.3 ± 0.6	-0.9 ± 0.7
95% confidence interval	-5.0 to -2.3	-2.3 to 0.5	-4.6 to -1.7	-2.3 to 0.5
Difference between groups (migraine days)	2.8		-2.4	
95% confidence interval	-0.8 to 4.7		-0.4 to 4.3	
Comparison between groups, *p*	0.0142 *		0.0246 *	
* $p < 0.05$. ** Subjects that completed 3 months of treatment without protocol deviation				

Table 5: Secondary Outcomes Excluding Subjects >15 Monthly Headaches

	Per protocol		Intention-to-treat**	
	Active	**Placebo**	**Active**	**Placebo**
n	28	18	34	18
Percentage of responders (reduction in monthly migraine days from baseline to third treatment month)				
Responders (≥50% reduction)	16 (57.1%)	6 (33.3%)	18 (52.9%)	6 (33.3%)
Comparison between the 2 groups, *p*	0.1146		0.1772	
% reduction (baseline vs. third month of treatment)	-46.1% ± 7.3%	-13.5% ± 14.2%	-40.8% ± 7.6%	-13.5% ± 14.2%
Comparison between the 2 groups, *p*	0.0336 *		0.0677	
Total monthly headache pain scores (baseline compared to third month of treatment)				
Total pain baseline month	45.8 ± 3.7	35.7 ± 4.1	44.4 ± 3.3	35.7 ± 4.1
Total pain third month	24.5 ± 2.9	26.7 ± 3.5	25.6 ± 2.7	26.7 ± 3.5
Change from baseline to third month	-21.3 ± 4.1	-8.9 ± 3.3	-18.7 ± 3.8	-8.9 ± 3.3
95% confidence interval	-29.7 to -12.9	-15.9 to -1.9	-29.0 to -6.0	-15.9 to -1.9
Comparison between the 2 groups, *p*	0.0382 *		0.0966	
Acute anti-migraine prescription drug intake (baseline compared to third month of treatment)				
n (subjects that took antimigraine prescription	24	16	29	16

drugs)				
Acute anti-migraine drugs intake (baseline)	7.3 ± 0.9	5.5 ± 1.6	7.3 ± 0.7	5.5 ± 1.6
Acute anti-migraine drug intake third month	3.6 ± 0.6	4.1 ± 1.5	3.9 ± 0.6	4.1 ± 1.5
Change from run-in to third month	-3.7 ± 0.7	-1.4 ± 0.8	-3.4 ± 0.6	-1.3 ± 0.8
95% confidence interval	-5.1 to -2.4	-3.0 to -0.2	-5.1 to -2.4	-5.1 to -2.4
p	0.0195 *		0.0464 *	

* $p < 0.05$.
** Subjects that completed 3 months of treatment without protocol deviation
Note: secondary endpoints are unadjusted

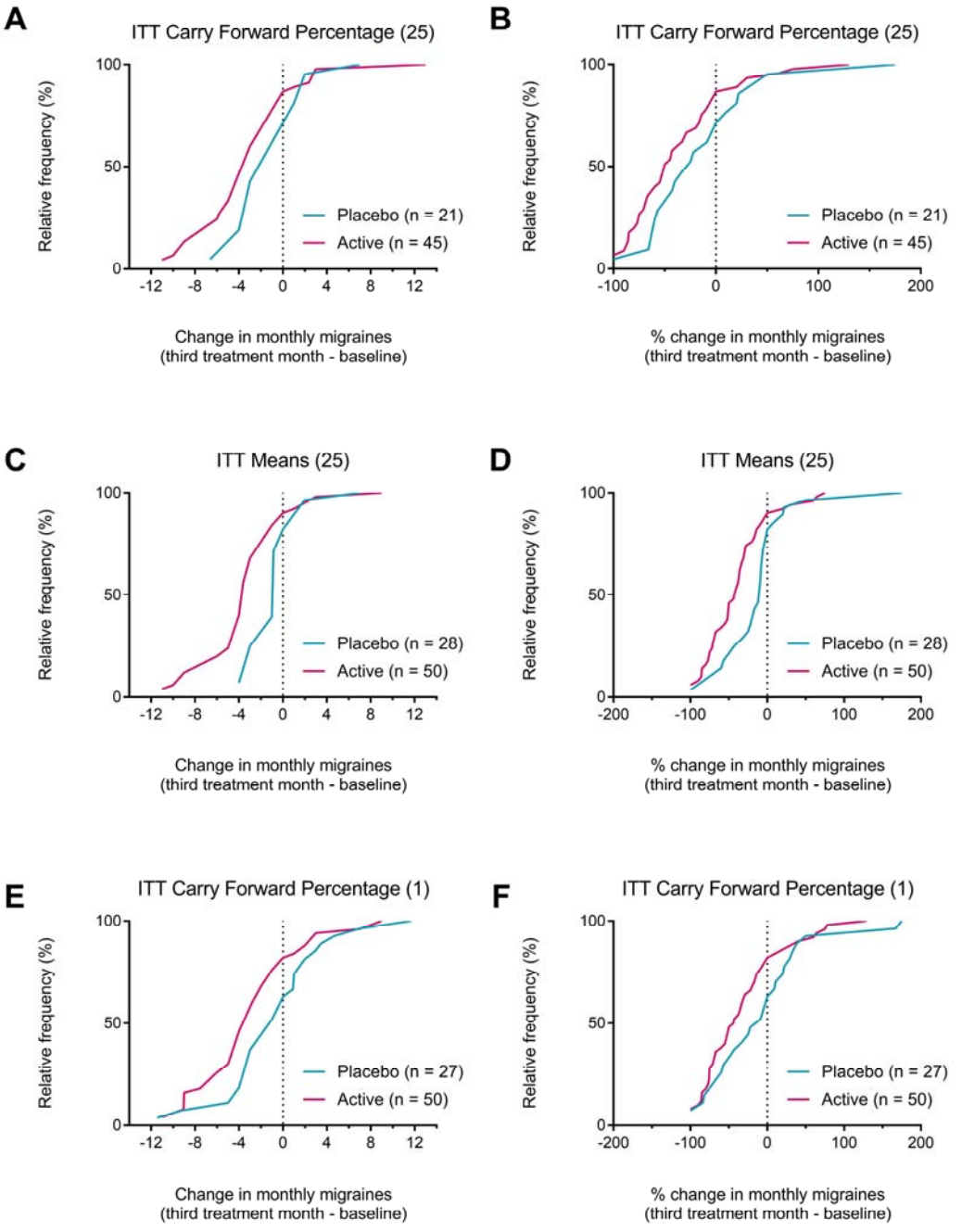

Figure 3: Monthly Reduction in Migraine Headache

A-B include subjects with at least 1 month of 25-days of data adherence that could be carried forward.
C-D calculated the mean within each treatment are for all subjects with 25-days of data adherence during the final treatment month. The mean for the treatment arm was used for all subjects within that treatment arm with less than 25 days of adherence during treatment month 3.
E-F calculated the percentage of migraine days given the diary data that existed for all subjects that had at least 1 day of data completed. If no data from treatment month 3 existed, data was carried forward from the last treatment month where data existed.

Pediatric Extrapolation

De Novo Summary (DEN170023)

In this premarket application, existing clinical data was leveraged to support the reasonable assurance of safety and effectiveness of the proposed device in the pediatric sub-population of patients age 12 years of age and older. The clinical trial for the TNM device was tested in subjects ages as young as 18 years. As part of this submission, the sponsor provided supporting information to justify extrapolation of the safety and effectiveness data to support use of this device in patients as young as 12 years old. Assessment of the adequacy of extrapolation included comparison of the migraine condition between the adolescent and adult patient populations, as well as assessment of safety. There is significant similarity in the migraine condition between the two groups, indicating that this device can also serve to provide prophylactic treatment for the adolescent population. Additionally, the safety profile is similar between both groups. Therefore, FDA agrees that based on the information presented, there is a reasonable assurance of safety and effectiveness for use by patients 12 years of age and older.

LABELING

The labeling for the TNM device is a single User Manual for both patients and physicians. It includes instructions for use and satisfies the requirements of 21 CFR § 801.109 for prescription devices. The labeling for the TNM device includes:

- Detailed instructions for use
- A summary of probable benefits
- A summary of probable risks
- A statement that all patients should have an ear exam prior to treatment
- Warnings identifying individuals who should not use the device and populations in which the safety and effectiveness of the device has not been evaluated
- A detailed summary of the clinical performance testing, including adverse events, complications, and probable side effects
- A warning that the long-term effects of chronic use of the device have not been evaluated
- Instructions on proper care of the device

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the thermal vestibular stimulator for headache and the measures necessary to mitigate these risks.

Identified Risk	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation Cleaning validation Labeling
Thermal injury	Labeling Non-clinical performance testing Thermal safety testing Technical specifications Software verification, validation, & hazard analysis
Ear tenderness and/or pruritus	Labeling Non-clinical performance testing

	Thermal safety testing Software verification, validation, & hazard analysis
Nausea and/or dizziness	Labeling Non-clinical performance testing Software verification, validation, & hazard analysis
Tinnitus	Labeling Non-clinical performance testing Software verification, validation, & hazard analysis

SPECIAL CONTROLS:

In combination with the general controls of the FD&C Act, the thermal vestibular stimulator for headache is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Performance testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety.
3. The technical parameters of the device, including waveform outputs and temperature limits, must be identified.
4. Cleaning validation of earpieces must be conducted.
5. Software verification, validation, and hazard analysis must be performed.
6. Labeling must include the following:
    a) Information on how the device operates and the typical sensations experienced during treatment;
    b) A detailed summary of the device's technical parameters; and
    c) Instructions for maintenance and cleaning of the device.

BENEFIT/RISK DETERMINATION

The risks of the device are based on data collected in a randomized, placebo-controlled clinical study as described above. There were no device-related serious adverse events observed in the study. The observed side effects that are possibly or probably related to use of the TNM device include: nausea, dizziness, ear tenderness and/or pruritus, tinnitus, worsened migraines, exacerbation of neck pain, change in blood pressure, and eye twitching. No adverse effects on mood, cognition, or balance were reported. The risks associated with long-term use of this device are unknown.

The probable benefits of the device are based on data collected in the randomized controlled clinical study which demonstrated that a significant percentage of subjects responded to treatment with a clinically and statistically significant reduction in migraine days per month. The results of the clinical study indicate that patients may experience a reduction in the frequency of migraine headache days, reduction in need for therapeutic migraine medication, and reduction in the subjective pain score.

Additional factors to be considered in determining probable risks and benefits for the TNM device include: 1) the degree of uncertainty associated with the benefits and risks is low, owing to the multi-center, triple-blinded, placebo-controlled, randomized clinical study that was provided to evaluate risks and benefits of the device and 2) alternative devices and medications that are approved for migraine prevention produce similar benefits to those obtained when using the TNM device. However, medications can produce problematic side effects such as cognitive changes.

Patient Perspectives

This submission did not rely on information regarding patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, the data support that for prophylactic treatment of episodic migraine headache in patients 12 and over, the probable benefits outweigh the probable risks for the ThermoNeuroModulation device. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the ThermoNeuroModulation device is granted and the device is classified under the following:

Product Code: QAR
Device Type: Thermal vestibular stimulator for headache
Class: II
Regulation: 21 CFR 882.5893